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UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

John Richards, Esq.
Ladas & Parry
26 West 61st Street
New York, NY 10023

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,663,318

MAILED

JAN 10 2004

#16

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,663,318, which claims the human drug product REMINYL® (galantamine hydrobromide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,064 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,064 days.

The period of extension has been calculated using the Food and Drug Administration (FDA) determination of the length of the regulatory review period published in the Federal Register of February 28, 2002 (67 Fed. Reg. 9301). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,089) + 519 \\ &= 1,064 \text{ days}\end{aligned}$$

Since the regulatory review period began October 6, 1996, after the patent issue date (May 5, 1987), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,663,318
Granted	:	May 5, 1987
Original Expiration Date	:	January 15, 2006

